



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mundy *et al.* Examiner: Haddad, Maher M
U.S. Pat. No.: 7,618,630 Serial No.: 10/086,217
Issued: November 17, 2009 Filed: February 21, 2002
Art Unit: 1644
Title: Methods of Treating Multiple Myeloma and Myeloma-Induced Bone Resorption
Using Integrin Antagonists

Mail Stop Petition

Commissioner for Patents

United States Patent and Trademark Office
Office of Petitions
Randolph Building
401 Dulany Street
Alexandria VA 22314

PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER
37 CFR 1.705(d)

The undersigned hereby petitions under 37 CFR 1.705(d) to request reconsideration of the patent term adjustment as indicated on the cover of U.S. Patent No. 7,618,630. In accordance with 37 CFR 1.705(d), this petition is being filed within two months of the date the patent issued. Applicants further submit for consideration, a statement of the facts involved as required under 37 CFR 1.705(b)(2).

The Commissioner is authorized to charge \$200 to the Deposit Account 19-4293 for the petition fee as set forth in 37 CFR 1.18(e). Should this fee be in error, the Commissioner is hereby authorized to debit or credit Deposit Account 19-4293.

Respectfully submitted,

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Steptoe & Johnson LLP
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Harold H. Fox
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**STATEMENT IN SUPPORT OF PETITION FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)**

The undersigned respectfully requests the reconsideration of the patent term adjustment ("PTA") for U.S. Patent No. 7,618,630 ("the '630 patent").

The term of the '630 patent has been extended by 72 days. The calculation for the current PTA calculated by the USPTO is 72 days based on 661 days of USPTO delay and 589 days of Applicant delay. See PTA calculation downloaded from PAIR, attached as Exhibit B.

Based on the recent decision in Wyeth v. Dudas, 580 F.Supp.2d 138 (D.D.C. 2008), aff'd, Wyeth v. Kappos, No. 2009-1120 (Fed. Cir. January 7, 2010) (both decisions attached as Exhibit A), patentees believe that patentees are entitled to an additional portion of patent term which amount to a total of **642 days**.

Support for the 642 days of PTA is justified as follows. Periods of delay that fall under 35 U.S.C. § 154 (b)(1)(A)(i)-(iv) are known as "A delays." "A delays" (or "A guarantee" or "A clause") include "a one-day extension of patent term for every day that issuance of a patent is delayed by failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action;" 35 U.S.C. § 154 (b)(1)(A)(i) and Wyeth v. Kappos, slip op. at 3. Periods of delay that fall under 35 U.S.C. § 154 (b)(1)(B) are known as "B delays" (or "B guarantee" or "B clause") and

include “a one-day term extension [] for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.” Id. The A delays and B delays are subject to the limitations of 35 U.S.C. § 154(b)(2)(A) which state that “[t]o the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” Slip op. at 3. The Federal Circuit found “no ambiguity in the terms ‘period of delay’ and ‘overlap’ and stated that “[t]he limitation in section 154(b) only arises when ‘periods of delay’ resulting from violations of the three guarantees ‘overlap.’” Slip op. at 7. Accordingly, a patent holder is entitled to PTA which includes the period of “A delay” + “B delay.” Id.

In accordance with the example examined in Wyeth v. Kappos, the undersigned provides the following calculation of PTA for consideration:

“A delay”:

April 21, 2003 (14 month date) to April 6, 2004 (mailing date of Restriction requirement) and PTO delay (31 +60 +219) days = **661 days**

“B delay”:

February 21, 2005 (3 years after patent application was filed) to September 14, 2006 (filing date of Request for Continued Examination) = **570 days**

Applicants’ Delay

589 days

Total PTA

A delay + B delay – Applicants’ Delay which is 661 days + 570 days – (589 days) which equals **642 days**.

For the reasons stated above, reconsideration of PTA is respectfully requested.
Should any further fees be required, the Commissioner is hereby authorized to debit or credit Deposit Account 19-4293.

Respectfully submitted,

Date: January 15, 2010
Steptoe & Johnson LLP
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Petlin Tan-Aguino REG NO 59,280 RV
Harold H. Fox
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EXHIBIT A

C

United States District Court,
 District of Columbia.

WYETH, et al., Plaintiffs,

v.

Jon W. DUDAS, Under Secretary of Commerce for
 Intellectual Property and Director of U.S. Patent and
 Trademark Office, Defendant.
 Civil Action No. 07-1492 (JR).

Sept. 30, 2008.

Background: Patent owners brought action challenging method used by Patent and Trademark Office (PTO) to calculate extensions of patent terms for certain specified kinds of PTO delay.

Holding: The District Court, James Robertson, J., held that extension of patent term based on PTO delay could exceed three years.

Ordered accordingly.

West Headnotes

[1] Patents 291 ⚡ 133

291 Patents

291 VI Term

291k133 k. Extension. Most Cited Cases

Patent and Trademark Office's (PTO) interpretation of statute providing extensions of patent terms for certain specified kinds of PTO delay was not entitled to Chevron deference. 35 U.S.C.A. § 154(b)(2)(C)(iii), (b)(3)(A).

[2] Patents 291 ⚡ 133

291 Patents

291 VI Term

291k133 k. Extension. Most Cited Cases

Extension of patent term for any administrative delay by Patent and Trademark Office (PTO) in issuing patent more than three years after filing date did not

necessarily overlap with extensions provided as result of PTO's failure to comply with enumerated statutory deadlines, and thus statutory prohibition against double-counting did not preclude patent applicants from claiming extensions in excess of three years. 35 U.S.C.A. § 154(b).

*138 David O. Bickart, Kaye Scholer LLP, Washington, DC, Patricia A. Carson, Kaye Scholer LLP, New York, NY, for Plaintiffs.

Fred Elmore Haynes, U.S. Attorney's Office, Washington, DC, for Defendant.

*139 MEMORANDUM OPINION

JAMES ROBERTSON, District Judge.

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. *See* 35 U.S.C. § 154 (1992) ("Every patent shall contain ... a grant ... for the term of seventeen years ... of the right to exclude others from making, using, or selling the invention throughout the United States...."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. *See* Pub.L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which referred to as the Patent Term Guarantee Act of 1999-provided for the adjustments that are at issue in this case. Pub.L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.^{FN1} *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period." ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

^{FN1}. Certain reasons for exceeding the

three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(b)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) **In general.**-To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed.Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of

delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed.Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this *141 example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

***Chevron* Deference**

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S.Ct. 2164, 150 L.Ed.2d 292 (2001), Congress has not

"delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, 126 S.Ct. 904, citing *Mead*, 533 U.S. at 226-27, 121 S.Ct. 2164. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed.Cir.1996).

[1] Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added)-that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT & T*, 512 U.S. 218, 229, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. §

154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, *142 the PTO defends its interpretation as essentially running the “period of delay” under subsection (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

[2] The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension “not exceed the actual number of days the issuance of the patent was delayed,” and by the PTO's view that “A delays” during the first three years of an applications' pendency inevitably lead to “B delays” in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet and administrative deadline, and again because that failure has pushed back the entire processing of the application into the “B period.” Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that-again from the PTO's viewpoint-the applicant is not “compensated” for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context-as distinct from the legislative history-suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided

before GATT. But it chose to write a “[g]uarantee of no more than 3-year application pendency,” 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable-they may even be consistent with Congress's intent-but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

D.D.C., 2008.
Wyeth v. Dudas
580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538

END OF DOCUMENT

United States Court of Appeals for the Federal Circuit

2009-1120

WYETH
and ELAN PHARMA INTERNATIONAL LIMITED,

Plaintiffs-Appellees,

v.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL
PROPERTY and DIRECTOR OF THE UNITED STATES PATENT
AND TRADEMARK OFFICE,

Defendant-Appellant.

Patricia A. Carson, Kaye Scholer LLP, of New York, New York, argued for plaintiffs-appellees. With her on the brief were Richard G. Greco; and David O. Bickart, of Washington, DC. Of counsel were Thomas E. Malone, Elan Pharmaceuticals, of South San Francisco, California; and Reem F. Jishi, Wyeth, of Madison, New Jersey.

Christine N. Kohl, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-appellant. On the brief were Tony West, Assistant Attorney General, Channing D. Phillips, Acting United States Attorney, and Scott R. McIntosh and Abby C. Wright, Attorneys. Of counsel on the brief were James A. Toupin, General Counsel, and Raymond T. Chen, Deputy General Counsel and Solicitor, United States Patent and Trademark Office, of Arlington, Virginia.

William G. James, II, Kenyon & Kenyon LLP, of Washington, DC, for amicus curiae Hospira, Inc. With him on the brief was Richard W. Ward.

Jeffrey B. Elikan, Covington & Burling LLP, of Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America, et al. With him on the brief were E. Edward Bruce and James P. Sullivan.

Appealed from: United States District Court for the District of Columbia

Judge James Robertson

United States Court of Appeals for the Federal Circuit

2009-1120

WYETH
and ELAN PHARMA INTERNATIONAL LIMITED,

Plaintiffs-Appellees,

v.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL
PROPERTY and DIRECTOR OF THE UNITED STATES PATENT
AND TRADEMARK OFFICE,

Defendant-Appellant.

Appeal from the United States District Court for the District of Columbia in case no. 07-CV-1492, Judge James Robertson.

DECIDED: January 7, 2010

Before RADER, PLAGER, and MOORE, Circuit Judges.

RADER, Circuit Judge.

I.

On summary judgment, the United States District Court for the District of Columbia held that plaintiffs Wyeth and Elan Pharma International Ltd. (collectively, “Wyeth”) were entitled to extended patent term adjustments under 35 U.S.C. § 154(b) due to the Patent and Trademark Office’s (the “PTO’s”) delay in prosecuting their patent applications. Because section 154(b) expressly permits this legal relief, this court affirms.

II.

In 1994, the law changed the effective term of a patent from seventeen years commencing from issuance to twenty years from filing. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). With the change came new ways of compensating patentees for PTO-caused delays during prosecution. Under the previous seventeen-year regime, PTO-caused delays could not affect patent terms because the term commenced upon issuance after any delays during patent acquisition. Under the twenty-year term, however, those delays consumed the effective term of a patent.

In 1999, the American Inventors Protection Act amended 35 U.S.C. § 154(b) to address this new problem. The new Act promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO. This promise took the form of three distinct “guarantees” in 35 U.S.C. § 154(b)(1):

(A) Guarantee of prompt Patent and Trademark Office responses.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to [meet deadlines specified in clauses (i)-(iv)] . . .

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States . . .

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals.--Subject to the limitations under paragraph (2) . . . the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(emphases added). To summarize, paragraph A (the “A guarantee” or “A clause”) promises “prompt [PTO] responses” by extending the term of the patent one day for each day the PTO does not meet certain examination deadlines in subdivisions (i)-(iv). Id. § 154(b)(1)(A). One of these deadlines, for instance, requires a first response to a filed application within fourteen months. See id. § 154(b)(1)(A)(i). Paragraph B (the “B guarantee” or “B clause”) extends the term of the patent one day for each day issuance is delayed due to the PTO’s failure “to issue a patent within 3 years after the actual filing date of the application in the United States.” Id. § 154(b)(1)(B). Last, paragraph C allows for adjustments relating to delays resulting from interference proceedings, secrecy orders, and appeals. Id. § 154(b)(1)(C). At issue in this case are the A and B guarantees.

Both the A and B clauses are expressly subject to paragraph 2’s “In general” limitation:

In general. To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Id. § 154(b)(2)(A) (emphasis added). In other words, this limitation restricts the period of adjustment when any of the “periods of delay” “overlap.” This case asks this court to interpret and enforce the guarantees in the face of an “overlap” and “periods of delay” under section 154(b)(2)(A).

Section 154(b)(3) of the statute directs the PTO to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.” Id. § 154(b)(3) (emphasis added). Under the guise

of that authority, the PTO promulgated 37 C.F.R. § 1.703(f) in 2000: “To the extent that periods of adjustment attributable to the [guarantees] overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.” (emphasis added). Other than adding the term “periods of adjustment,” this language repeated the text of section 154(b)(2)(A). The regulations later defined “periods of adjustment” as “the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed” 37 C.F.R. § 1.703(b) (2000). The regulation supplied no explanation about implementation or application of these rules.

In 2004, the PTO amended the regulation to replace “periods of adjustment” with “periods of delay.” 69 Fed. Reg. 21706 (2004). The PTO contended that this substitution clarified the regulation:

The language of former § 1.703(f) misled applicants into believing that [periods of A-delay] and [periods of B-delay] were overlapping only if the [period of A-delay] occurred more than three years after the actual filing date of the application. If an application is entitled to a [B]-adjustment . . . the entire period during which the application was pending before the [PTO] . . . , and not just the period beginning three years after the actual filing date of the application; is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).

Id. (emphasis added). Thus, the “period of delay,” according to the PTO’s new definition, caused the B guarantee to start with the filing of the application, not three years later. Under that interpretation, “overlap” between A adjustments and B adjustments can arise and begin during the pendency of the patent application. For example, if a patent entitled to twenty days of A adjustments issues twenty days after the three year mark, then it is only entitled to a total of twenty days of adjustment. In

other words, the entire period of A delay “overlaps” with the entire period of B delay. Using this framework, the PTO uses either the greater of the A delay or B delay to determine the appropriate adjustment but never combines the two.

Wyeth and Elan Pharma are the owners of U.S. Patent Nos. 7,179,892 (the “’892 patent”) and 7,189,819 (the “’819 patent”)—inventions that treat Alzheimer’s disease. During the prosecution of each of their respective applications, the PTO undisputedly caused delays that gave the applicants entitlement to both A and B guarantees.

For the ’892 patent, the PTO calculated 610 days of A delay and 345 days of B delay. Of the 610 days of A delay, 51 occurred more than three years after the application was filed. During the prosecution, the applicant caused 148 days of delay. Thus, under section 154(b)(2)(C), any adjustment must be reduced by that amount. See 35 U.S.C. 154(b)(2)(C). Under its greater-of-A-or-B rubric, the PTO calculated the total adjustment at 462 days—i.e., 610 (the greater of A or B) - 148 (applicant delay). According to Wyeth, however, the “period of delay” for purposes of the B clause could not have started until three years after the application’s filing date. For that reason, the only possible “overlap” was any A delay occurring after the three-year mark. Because only 51 days of A delay occurred after the three year mark for the ’892 patent, the adjustment, according to Wyeth, should have been 756 days—i.e., 610 (A delay) + 345 (B delay) - 51 (“overlap”) - 148 (applicant delay).

For the ’819 patent, the PTO calculated 336 days of A delay and 827 days of B delay. Of the 336 days of A delay, 106 occurred after the three-year mark. In this case, the applicant caused 335 days of delay. The greater-of-A-or-B rubric yields an adjustment period of 492 days—i.e., 827 (the greater of A or B) - 335 (applicant delay).

Wyeth contends the adjustment period should have been 722 days—i.e., 336 (A delay) + 827 (B delay) - 106 (“overlap”) - 335 (applicant delay).

After filing petitions for reconsideration of the adjustments with the PTO, Wyeth filed the instant action in the District Court for the District of Columbia seeking an order directing the PTO to grant an adjustment per Wyeth's interpretation. Both parties filed motions for summary judgment. Citing section 154(b)(3) as evidence of a delegation of authority to draft regulations, the PTO sought Chevron deference for its interpretation. See Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837 (1984).

The district court sided with Wyeth, finding first that the PTO “does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency.” Wyeth v. Dudas, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) (citing Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996)). The district court further found that even if Chevron was applicable, it would have rejected the PTO's interpretation as contrary to the plain language of the statute. As the district court put it: “The problem with the PTO's interpretation is that it considers the application delayed under [the B guarantee] during the period before it has been delayed.” Id. at 142 (emphasis in original).

III.

This court reviews a grant of summary judgment without deference. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998). Summary judgment is only appropriate if the court determines that there “is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Because both parties in the instant case perceive no genuine

issues of material fact, this court need only decide the question of law decided by the district court. “That question is one of statutory interpretation, one that an appellate court can independently determine without deference to the trial court’s interpretation.” Glaxo Operations UK Limited v. Quigg, 894 F.2d 392, 395 (Fed. Cir. 1990) (citing Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed. Cir. 1989)).

“As always, the ‘starting point in every case involving construction of a statute is the language itself.’” United States v. Hohri, 482 U.S. 64, 68 (1987) (quoting Kelly v. Robinson, 479 U.S. 36, 43 (1986)). When the terms of a statute are unambiguous, “judicial inquiry is complete, except ‘in rare and exceptional circumstances.’” Rubin v. United States, 449 U.S. 424, 430 (1981) (quoting TVA v. Hill, 437 U.S. 153, 187 n.33 (1978)). “Absent a clearly expressed legislative intention to the contrary, [the statute’s plain] language must ordinarily be regarded as conclusive.” Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980).

This court detects no ambiguity in the terms “periods of delay” and “overlap.” Each term has an evident meaning within the context of section 154(b). The limitation in section 154(b) only arises when “periods of delay” resulting from violations of the three guarantees “overlap.” 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply. Thus, this court can easily detect any overlap by examining the delay periods covered by the A and B guarantees.

A violation of the A guarantee—delays in meeting examination deadlines—begins with a “failure of the [PTO]” to meet one of the deadlines specified in subparagraphs (i)–(iv). Id. § 154(b)(1)(A). It ends when “the action described . . . is

taken.” Id. The “period of delay” for purposes of the A clause therefore runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action.

Correspondingly, a violation of the B guarantee—the one at the heart of the issue in this case—begins when the PTO fails “to issue a patent within 3 years after the actual filing date of the application in the United States” Id. § 154(b)(1)(B). It ends when “the patent is issued.” Id. The “period of delay” under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.

Reading this framework into section 154(b)’s limitation provision makes it clear that no “overlap” happens unless the violations occur at the same time. Each “period of delay” has its own discrete time span whose boundaries are defined in section 154(b)(1). That is, each has a start and an end. Before the three-year mark, no “overlap” can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not “overlap” under section 154(b)(2).

Under the PTO’s strained interpretation, B delay can occur anytime after the application is filed. To the contrary, the language of section 154(b) does not even permit B delay to start running until three years after the application is filed. The PTO’s position cannot be reconciled with the language of the statute. Thus, returning to the district court’s decision, this time with affirming approval: “The problem with the PTO’s interpretation is that it considers the application delayed under [the B guarantee] during the period before it has delayed.” Wyeth, 580 F. Supp. 2d at 142 (emphasis in original).

The PTO defends its interpretation by arguing that A delays during the first three years of prosecution ultimately lead to B delays after the three-year mark from filing. Put differently, it would be double counting if A and B delays were both used to adjust because A delays “cause” B delays. In that vein, the PTO highlights various scenarios where a hypothetical patentee appears to receive some type of windfall adjustment under the statute despite being in a similar position as other applicants who receive no similar adjustment. Indeed, the statute requires as much. Nonetheless, this court perceives potential perverse results as well under the PTO’s suggested interpretations. Under certain scenarios, both the PTO’s interpretation and the statute itself result in some imbalanced treatment of similarly-situated patentees.

For example, the language of section 154(b) presents a slight imbalance in the following hypothetical: suppose Applicant 1 receives a patent 3 years and 30 days after filing an application. In prosecuting the application, Applicant 1 incurred 30 days of A delay before the three-year mark. In the same hypothetical situation, suppose Applicant 2 also receives a patent 3 years and 30 days after filing an application but incurred no A delay during prosecution. Notably, both patents issued the same amount of time from filing—3 years and 30 days. Nonetheless, Applicant 1 would receive a 60 day adjustment whereas Applicant 2 would only receive a 30 day adjustment meaning Applicant 1’s effective term would be 30 days longer than Applicant 2.

By the same token, under the PTO’s counter-statutory interpretation, suppose Applicant 1 incurs 400 days of A delay before the three-year mark with the application issuing exactly three years after filing. Suppose Applicant 2 also incurs 400 days of A delay before the three-year mark, but in addition incurs a one-year delay by the PTO

after the three-year mark. Despite the fact each applicant incurred the same A delay, under the PTO's interpretation, Applicant 1's effective term would be a full year greater than Applicant 2's effective term. Simply put, the additional B delay incurred by Applicant 2 produces a shorter effective term.

Regardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct. See Harbison v. Bell, 129 S. Ct. 1481, 1493-94 (2009) (Thomas, J., concurring) (quoting Eldred v. Ashcroft, 537 U.S. 186, 222 (2003) ("Even if the proper interpretation of a statute upholds a 'very bad policy,' it 'is not within our province to second-guess' the 'wisdom of Congress' action' by picking and choosing our preferred interpretation from among a range of potentially plausible, but likely inaccurate, interpretations of a statute.")).

The PTO also passingly refers to the second clause of section 154(b)(2)(A) for support: "the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). While the PTO's argument on this point is unclear, that language does not provide any support for its interpretation. Significantly, the second clause of section 154(b)(2)(A) only takes effect upon satisfaction of the first clause. See id. § 154(b)(2)(A) ("To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap") (emphasis added). Viewed in this light, a "delay" must refer consistently to the violation of either the A or B guarantees. "[T]he actual number

of days the issuance of the patent was delayed” therefore refers to each day covered by a “period of delay” in the first clause with no such day counted twice.

This court has also examined the legislative history of the 1999 Act but finds nothing to rescue the PTO’s cause. In the first place, only a “most extraordinary showing of contrary intentions” by Congress justifies a departure from the plain language of a statute. Garcia v. United States, 469 U.S. 70, 75 (1984). Far from intentions contrary to the meaning of section 154(b), the legislative history generally supports the interpretation required by the statutory language itself. The AIPA’s section-by-section analysis states:

Accordingly, subtitle D removes the 10-year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more.

H.R. Rep. No. 106-464, at 125 (1994) (emphases added). From this, it is apparent that the statutory language should provide a minimum seventeen-year term for most patents. The outcome suggested by the language itself effectuates this goal by ensuring such a minimum term unless the applicant caused delays.

The PTO urges this court to read that passage in view of the 25-month average patent pendency at that time—that is, most patents received more than a seventeen-year term because of the shorter prosecution periods. Even taking that context into account, this court notes that the PTO’s interpretation effectively creates a seventeen-year term cap where B delays are greater than A delays. In other words, any A delay before the three-year mark causes PTO delays in issuance beyond the three-year

mark—thereby violating the B guarantee. Together, these effects, under the PTO's desire to aggregate A and B delays, reduce the effective term of the patent towards seventeen years. The passage from the House report does not expressly preclude that type of effective cap, but the context suggests a very different goal of supplying adequate protection that will often be “considerably more” than the PTO's effective cap. In any event, the House report does not produce any “extraordinary showing of contrary intentions.” Moreover, if the Act intended to create a seventeen-year cap, it could have easily done so with just a few words.

The PTO next highlights the belated addition of the B guarantee into section 154(b) for support. Before enactment of AIPA, section 154(b) only provided extensions for the category that now fall under C adjustments. See 35 U.S.C. § 154(b)(1)-(2) (1996). The earlier versions of AIPA added only A delays. See S. 507, 105th Cong., 143 Cong. Rec. S2678, S2696-97 (Mar. 20, 1997). Not long afterwards, B adjustments appeared in drafts of section 154(b). See H.R. 400, 105th Cong., 143 Cong. Rec. H1629, H1651 (April 17, 1997). According to the PTO, this legislative history suggests that Congress did not intend to give patentees already eligible for A adjustments additional compensation where the A delay occurred during the first three years of prosecution. Even if these ambiguous timing observations suggested some kind of substantive difference in the meaning of section 154(b), they would be wholly irrelevant to interpretation of the law itself. Such opaque timing observations hardly amount to a “most extraordinary showing of contrary intentions,” especially when the language of the statute trumpets its meaning by itself. See Harbison, 129 S. Ct. at 1494 (Thomas, J., concurring) (“And Congress’ silence certainly does not empower us to go even farther

and incorporate such an assumption into the text of these provisions.”). In sum, legislative history—always a very dull instrument for extracting the essence of statutory meaning—provides no reason to depart from the language of section 154(b).

Last, the PTO contends that its interpretation is entitled to deference under either Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) or Skidmore v. Swift & Co., 323 U.S. 134 (1944). Because the language of the statute itself controls this case and sets an unambiguous rule for overlapping extensions, this court detects no reason to afford special deference to the PTO’s interpretation. See Smith v. City of Jackson, Miss., 544 U.S. 228, 267 (2005) (quoting Pub. Employees Ret. Sys. of Ohio v. Betts, 492 U.S. 158, 171 (1989)) (“Of course, it is elementary that ‘no deference is due to agency interpretations at odds with the plain language of the statute itself.’”).

IV.

This court therefore affirms the judgment of the district court. Section 154(b)’s language is clear, unambiguous, and intolerant of the PTO’s suggested interpretation. For that reason, this court accords no deference to the PTO’s greater-of-A-or-B rubric.

AFFIRMED

EXHIBIT B

10/086,217	METHODS OF TREATING MULTIPLE MYELOMA AND MYELOMA-INDUCED BONE RESORPTION USING INTEGRIN ANTAGONISTS	01-08-2010::18:50:00
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/086,217

Filing or 371(c) Date:	02-21-2002	USPTO Delay (PTO) Delay (days):	661
Issue Date of Patent:	11-17-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	589
Post-Issue Petitions (days):	+0	Total PTA (days):	72
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
10-28-2009	PTA 36 Months	219	
11-17-2009	Patent Issue Date Used in PTA Calculation		
10-12-2009	Dispatch to FDC	↑	
10-12-2009	Application Is Considered Ready for Issue	↑	
10-05-2009	Issue Fee Payment Verified	↑	
10-05-2009	Issue Fee Payment Received	↑	
08-07-2009	Sequence Forwarded to Pubs on Tape	↑	
07-29-2009	Mail Post Card	↑	
07-22-2009	Change in Power of Attorney (May Include Associate POA)	↑	
07-21-2009	Mail Notice of Allowance	↑	
07-16-2009	Document Verification	↑	
07-16-2009	Notice of Allowance Data Verification Completed	↑	
04-29-2009	Information Disclosure Statement considered	↑	
04-29-2009	Electronic Information Disclosure Statement	↑	
05-20-2009	Date Forwarded to Examiner	↑	
04-29-2009	Request for Continued Examination (RCE)	↑	
05-20-2009	Disposal for a RCE / CPA / R129	↑	
04-29-2009	Information Disclosure Statement (IDS) Filed	↑	
04-29-2009	Workflow - Request for RCE - Begin	↑	
03-11-2009	Email Notification	↑	
03-11-2009	TC Return to Pubs	↑	
03-11-2009	Mail Miscellaneous Communication to Applicant	↑	
03-06-2009	Miscellaneous Communication to Applicant - No Action Count	↑	
02-25-2009	Pubs Case Remand to TC	↑	
02-13-2009	Sequence Forwarded to Pubs on Tape	↑	
01-29-2009	Electronic Review	↑	
01-29-2009	Email Notification	↑	
01-29-2009	Email Notification	↑	
01-29-2009	Mail Examiner Interview Summary (PTOL - 413)	↑	
01-29-2009	Mail Notice of Allowance	60	

01-09-2009	Document Verification	↑	
01-09-2009	Notice of Allowance Data Verification Completed	↑	
01-09-2009	Case Docketed to Examiner in GAU	↑	
10-30-2008	Examiner Interview Summary Record (PTOL - 413)	↑	
01-02-2009	Date Forwarded to Examiner	↑	
12-30-2008	Supplemental Response		153
10-24-2008	Information Disclosure Statement considered	↑	
10-24-2008	Information Disclosure Statement (IDS) Filed	↑	
11-01-2008	Date Forwarded to Examiner	↑	
10-24-2008	Supplemental Response	↑	
10-24-2008	Information Disclosure Statement (IDS) Filed	↑	
10-21-2008	Email Notification	↑	
10-21-2008	Mail Examiner Interview Summary (PTOL - 413)	↑	
10-15-2008	Examiner Interview Summary Record (PTOL - 413)	↑	
08-30-2008	Date Forwarded to Examiner	↑	
07-30-2008	Response after Non-Final Action		91
07-30-2008	Request for Extension of Time - Granted	↑	
07-30-2008	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	↑	
07-01-2008	Email Notification	↑	
07-01-2008	Change in Power of Attorney (May Include Associate POA)	↑	
06-27-2008	Correspondence Address Change	↑	
01-30-2008	Mail Non-Final Rejection		↑
01-29-2008	Non-Final Rejection		
11-27-2007	Date Forwarded to Examiner		
11-27-2007	Date Forwarded to Examiner		
10-31-2007	Request for Continued Examination (RCE)		
11-27-2007	Disposal for a RCE / CPA / R129		
11-15-2007	Correspondence Address Change		
10-31-2007	Workflow - Request for RCE - Begin		
08-29-2007	Mail Final Rejection (PTOL - 326)	31	
08-23-2007	Final Rejection	↑	
07-11-2007	Date Forwarded to Examiner	↑	
03-29-2007	Response after Non-Final Action		29
03-29-2007	Request for Extension of Time - Granted		↑
04-25-2007	Change in Power of Attorney (May Include Associate POA)		↑
04-23-2007	Correspondence Address Change		↑
04-19-2007	Change in Power of Attorney (May Include Associate POA)		↑
11-30-2006	Mail Non-Final Rejection		↑
11-27-2006	Non-Final Rejection		
09-14-2006	Information Disclosure Statement considered		
05-18-2005	Information Disclosure Statement considered		

09-14-2006	Reference capture on IDS	
09-14-2006	Information Disclosure Statement (IDS) Filed	
09-14-2006	Information Disclosure Statement (IDS) Filed	
09-14-2006	Oath or Declaration Filed (Including Supplemental)	
09-25-2006	Date Forwarded to Examiner	
09-25-2006	Date Forwarded to Examiner	
09-14-2006	Request for Continued Examination (RCE)	
09-25-2006	Disposal for a RCE / CPA / R129	
09-14-2006	Request for Extension of Time - Granted	
09-14-2006	Workflow - Request for RCE - Begin	
02-14-2006	Notice of Appeal Filed	95
02-14-2006	Request for Extension of Time - Granted	↑
05-18-2005	Information Disclosure Statement (IDS) Filed	↑
05-18-2005	Information Disclosure Statement (IDS) Filed	↑
08-11-2005	Mail Final Rejection (PTOL - 326)	↑
08-08-2005	Final Rejection	
05-26-2005	Date Forwarded to Examiner	
05-18-2005	Response after Non-Final Action	92
05-18-2005	Request for Extension of Time - Granted	↑
11-15-2004	Mail Non-Final Rejection	↑
11-15-2004	Non-Final Rejection	
12-28-2004	Date Forwarded to Examiner	
11-12-2004	Supplemental Response	35
10-25-2004	Date Forwarded to Examiner	↑
10-08-2004	Response to Election / Restriction Filed	94
10-08-2004	Request for Extension of Time - Granted	↑
10-08-2004	Workflow incoming amendment IFW	↑
04-06-2004	Mail Restriction Requirement	351
04-05-2004	Requirement for Restriction / Election	↑
03-08-2004	Case Docketed to Examiner in GAU	↑
11-04-2003	Correspondence Address Change	↑
10-20-2003	Information Disclosure Statement (IDS) Filed	↑
10-20-2003	Information Disclosure Statement (IDS) Filed	↑
10-20-2003	Preliminary Amendment	↑
07-10-2003	IFW TSS Processing by Tech Center Complete	↑
07-05-2002	Information Disclosure Statement (IDS) Filed	↑
07-05-2002	Information Disclosure Statement (IDS) Filed	↑
06-21-2002	Information Disclosure Statement (IDS) Filed	↑
06-21-2002	Information Disclosure Statement (IDS) Filed	↑
06-21-2002	Preliminary Amendment	↑
02-21-2002	Preliminary Amendment	↑

10-31-2002	Case Docketed to Examiner in GAU	↑
07-29-2002	Application Dispatched from OIPE	↑
07-24-2002	Application Is Now Complete	↑
05-02-2002	Additional Application Filing Fees	↑
05-02-2002	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	↑
07-17-2002	CRF Is Good Technically / Entered into Database	↑
04-12-2002	Notice Mailed--Application Incomplete--Filing Date Assigned	↑
03-28-2002	IFW Scan & PACR Auto Security Review	↑
03-19-2002	IFW Scan & PACR Auto Security Review	↑
02-21-2002	Initial Exam Team nn	↑

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